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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,769

12/01/2005

Sylvie Sauvaigo

1169-037

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05/07/2010

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EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

05/07/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,769	<b>Applicant(s)</b> SAUVAIGO, SYLVIE	
	<b>Examiner</b> Michele K. Joiike	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/25/10</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed January 25, 2010.

Claims 22-50 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 23, 2009 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-50 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for reasons of record, and for the reasons stated below.

### ***Response to Arguments Concerning Claim Rejections – 35 USC § 112(2)***

Applicant's arguments filed January 25, 2010 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants argue that the repair solution always contains an essential component, and lack of repair enzymes in the solution can still provide information concerning the individual.

Applicants argue that a number of diseases are associated with faulty DNA repair systems. Using the method of claim 22, it is possible to determine whether the pathology exhibited by the individual is due to a faulty DNA repair system.

Applicant's arguments have not been found persuasive for the following reasons.

All of the components are optional, except for labeled nucleotide triphosphates. It is unclear how the triphosphates by themselves are repairing the DNA lesion. "Repair solution" indicates that there is something in the solution to aid in repairing. Applicants may consider removing the word "repair" before "solution", instead of making all of the components optional; consider putting them in a Markush group. Furthermore, the method is performed in vitro, so there is no way to determine if an individual possesses functional individual repair enzymes, as there is no individual.

As for claim 42, Applicants are not requiring the DNA sample to be obtained from an individual. DNA plasmids containing lesions are created. There is no correlation between the lesions created and a disease.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 stand rejected under 35 U.S.C.

103(a) as being unpatentable over US 2002/0022228 in view of Calsou et al.

Claims 26-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/00222288 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Douki et al.

Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of MPEP 2144.05.

Claims 34-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Chiu et al.

Claims 32 and 37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Zierdt et al.

Claims 39 and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Gelfand et al.

Claims 45 and 46 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of MPEP 2144.05.

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Claim 48 stands rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Yershov et al.

Claim 49 stands rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Randerath et al.

These rejections are maintained for reasons of record, and for the reasons stated below.

***Response to Arguments Concerning Claim Rejections – 35 USC § 103(a)***

Applicant's arguments filed January 25, 2010 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants argue that US 2002/0022228 and Calsou et al are directly contrary to each other regarding the nature of the DNA target. US 2002/0022228 teaches using oligos and Calsou et al teach using supercoiled DNA. Neither reference suggests using the other. Because of this the Examiner is using hindsight reconstruction to arrive at the claimed invention. Furthermore, US 2002/0022228 and Calsou et al contain different types of repair mechanisms, and one of skill in the art would be dissuaded from using the other. There is no cited art that teaches assaying both NER and BER activity.

The assay claimed has been designed to be as specific as possible to the excision and resynthesis DNA repair capacities of the biological medium being tested,

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and one of the most important aspects of the claimed method is that DNA repair mechanisms associated with strand breaks and nuclease activity are not measured.

Neither reference addresses this.

The method in claim 22 is superior because a large number of mutation types are created, and therefore, one can accurately quantify all the various excision and resynthesis repair capacities of the biological medium.

Lastly, none of the other references cited remedy the deficiencies of US 2002/0022228 and Calsou et al.

Applicant's arguments have not been found persuasive for the following reasons.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). If US 2002/0022228 taught using supercoiled DNA, the examiner would not have needed to combine the teachings of US 2002/0022228 with Calsou et al. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.

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See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, assessing DNA excision and repair of supercoiled plasmids was known at the time of invention, so combining Calsou et al with US 2002/0022228 is obvious as explained in the prior office action. Both teach excision repair, and one of skill in the art would know that different repair mechanisms would be required depending on the type of lesion and DNA that existed. One would be motivated to combine the references because Calsou et al teach that supercoiled plasmids allow for more efficient repair.

Applicants are not claiming a specific assay. The method in claim 22 is general and broad. No particular treatment is specified, and only one treatment is required. Components of the repair solution are even optional, as it is not known what will be needed to repair the solution (as argued by Applicants). The types of lesions are not known, because the treatment used can be one of many, until the lesion is characterized in step b. The claim does not rule out any particular DNA repair mechanism. Furthermore, it is unknown how many mutations types occur.

Lastly, there are no deficiencies to cure as just discussed.

### ***Allowable Subject Matter***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/  
Primary Examiner, Art Unit 1636

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